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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,103	08/08/2001	David M. Goldenberg	018733-1055	9967

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,103	GOLDENBERG ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/8/2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 7 are drawn to a method of treating chronic myelocytic leukemia (CML) by administering a therapeutic composition comprising pharmaceutical carrier and at least one naked anti-granulocyte antibody, classified in 424, subclass 131.1.

II. Claims 6 and 22, are drawn to a method of treating acute myelocytic leukemia (AML) or acute promyelocytic leukemia (APML) by administering a therapeutic composition comprising an anti-granulocyte antibody and an inducing agent, classified in class 424, subclass 153.1, for example.

III. Claims 1, 8, 10-13, and 23 are drawn to a method of treating CML by administering a therapeutic composition further comprising the administration of an immunoconjugate, wherein the immunoconjugate further comprises a cytokine moiety, classified in 424, subclass 1.37, for example.

IV. Claims 1, 9, 17, and 24 are drawn to a method of treating CML by administering a therapeutic composition for treating CML, further comprising the administration of chemotherapy, classified in ***, subclass 183.1, for example.

V. Claims 1, 8, 14-16 are drawn to a method of treating CML by administering a therapeutic composition for treating CML, further comprising the administration of fusion protein, classified in 424, subclass 192.1

VI. Claims 18-21 are drawn to a method of treating CML by administering a therapeutic composition for treating CML, wherein the therapeutic composition comprises two naked anti-granulocyte antibodies 424, subclass 136.1 for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to treating a disease with different type of products. The inventions of group I is directed at treating CML in a patient with a therapeutic composition comprising a single active ingredient, an anti-granulocyte antibody. The inventions of groups III-VI are drawn to methods of treating CML in a patient, with a therapeutic composition comprising at least two active ingredients (i.e. antibody and immunoconjugate, antibody and chemotherapy, antibody and fusion protein, antibody and antibodies). These products are structurally different and are composed of separate compounds. Therefore the methods of using these are novel and unobvious in view of each other and are patentably distinct one from the other.

4. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and effects. Group I is drawn to a method of treating CML in a patient, with a therapeutic composition comprising an anti-granulocyte antibody. Group II is drawn to a method of treating AML or APML in a patient with a therapeutic composition comprising an anti-granulocyte antibody and an inducing agent. These methods are directed at different diseases and therefore act of separate mechanism associated with the diseases. Furthermore, the two inventions (group I and group II) have different outcomes or effects, namely, the prevention and/ or treatment of CML and AML/APML.

5. Because these inventions are distinct for the reasons given above and the search required for Groups I-VI are not required for each other, Groups I-VI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention

Group I:
where the type of antibody is:

i. MN-3
ii. MN-2
iii. MN-15
iv. NP-1
v. NP-2

where the type of antibody is:

i. subhuman primate
ii. murine monoclonal
iii. chimeric
iv. humanized
v. human

Group II:
where the type of cytokine moiety is:

i. IL-1
ii. IL-2
iii. IL-3
iv. IL-6
v. IL-10
vi. IL-12
vii. Interferon α
viii. Interferon β
ix. Interferon γ
x. GM-CSF

where the type of radionucleotide is:

i. ^{198}Au
ii. ^{32}P
iii. ^{125}I
iv. ^{131}I
v. ^{90}Y
vi. ^{186}Re
vii. ^{188}Re
viii. ^{67}Cu
ix. ^{211}At
x. ^{213}Bi
xi. ^{225}Ac

Group V:
where the type of fusion protein is:

i. antibody-immunomodulator fusion protein
ii. antibody-toxin fusion protein

where the type of immunoconjugate conjugate is:

i. anti-NCA 90 antibody and Rnase
ii. anti-CD33 antibody and calicheamicin

Group IV:
where the type of chemotherapy drug is:

i. daunorubicin
ii. cytarabine
iii. 6-thioguanine
iv. mitoxantrone
v. diaziquone
vi. idarubicin
vii. homoharringtonine
viii. Amsacrine
ix. busulfan
x. yydroxyurea
xi. cyclophosphamide
xii. etoposide
xiii. vincristine
xiv. procarbazine
xv. prednisone
xvi. carmustine
xvii. doxorubicin
xviii. methotrexate
xix. bleomycin
xx. dexamethasome
xxi. phenyl butyrate
xxii. brostatin-1
xxiii. calicheamicin
xxiv. leacovorin

These species are distinct because their structures, modes of action, and specificities are different. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

GEETHA P. BANSAL
PRIMARY EXAMINER

Christopher Yaen
Art Unit 1642
February 25, 2002